IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327 MDL 2327

THIS DOCUMENT RELATES TO:

ETHICON WAVE 5 CASES LISTED IN PLAINTIFFS' EXHIBIT A

JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE OR OTHERWISE LIMIT THE OPINIONS AND TESTIMONY OF STEVEN GOLDWASSER, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") respectfully submit this Memorandum in Opposition to Plaintiffs' Motion to Exclude or Otherwise Limit the Opinions and Testimony of Defense Expert Steven Goldwasser, M.D. ("Dr. Goldwasser"). (Pls.' Motion [ECF No. 4365]; Exs. A-F [ECF Nos. 4365-1, 4365-2, 4365-3, 4365-4, 4365-5, 4354-6]; Memorandum [ECF No. 4372].)¹

INTRODUCTION

Plaintiffs seek to bar the testimony of Dr. Goldwasser, who Ethicon offers as a general expert on the design, safety, and efficacy of TVT and TVT-Exact. Plaintiffs support their motion by mischaracterizing the scope and basis for Dr. Goldwasser's opinions – incorrectly claiming he provides opinions about FDA regulations and suggesting his opinions on material properties of

¹ Because Plaintiffs' Motion "adopt[s] and incorporate[s]" their Wave 4 Motion to Exclude Expert Testimony of Dr. Goldwasser and their Memorandum of Law in support thereof, Pls.' Motion [ECF No. 3677]; Exs. A-C [ECF Nos. 3677-1, 3677-2, 3677-3]; Memorandum [ECF No. 3678], Ethicon hereby adopts and incorporates its Memorandum of Law in Opposition to Plaintiffs' Wave 4 Motion [ECF No. 3754].

polypropylene mesh are based solely on his personal experience. Contrary to Plaintiffs' framing of these opinions, Dr. Goldwasser properly combines his experience as a surgeon, teacher, and inventor and his review of the medical literature – including Level 1 studies – to not only identify the commonly known risks but to opine on whether the IFUs of TVT and TVT-Exact disclose those enumerated risks from a clinical perspective. Likewise, Dr. Goldwasser's experience and review of the literature qualifies him to challenge the scientific basis for Plaintiffs' assertions that Ethicon's mesh devices' material properties, including degradation, mesh contraction, cytotoxicity, and laser and mechanical cut mesh, have negative clinical impact on patients. Ultimately, his opinions would be very instructive to the jury and should be admitted at trial.

DR. GOLDWASSER'S BASES FOR HIS EXPERT OPINION

Dr. Goldwasser is board-certified in obstetrics, gynecology, and female pelvic medicine and reconstructive surgery. (Pls.' Ex. B (Goldwasser Report) at 1.) He completed his residency in obstetrics and gynecology and is fellowship trained in female pelvic medicine and reconstructive surgery. (*Id.*) He started the division of Urogynecology at the University of Florida and continues to teach there as a clinical instructor. (*Id.*) Dr. Goldwasser has been trained in a large variety of female pelvic medicine and reconstructive treatment "including vaginal, abdominal, laparoscopic, robotic, and non-surgical approaches for treating pelvic organ prolapse and urinary incontinence." (*Id.* at 2.) In addition, he has been trained on various testing, including urodynamic testing, uroflowmetry, post-void residual measurements, cystometric testing, leak point pressure measuring, and pressure flow studies. (Pls.' Ex. D (Goldwasser Dep.) 13:6-14:4.) During his training and career, Dr. Goldwasser has designed and implemented various techniques involving native tissue repair and augmentation procedures

using biologic graft and synthetic graft materials. (*Id.* at 2.) These experiences led to Dr. Goldwasser developing and implementing devices and techniques for reconstructive pelvic surgery, including co-inventing EXAIR, a novel polypropylene mesh graft-based approach for treating vaginal prolapse. (*Id.* at 4.)

Thus far in his surgical career, Dr. Goldwasser has performed "easily over 1000 TVT procedures (predominantly the original TVT and the TVT Exact) with excellent results." (*Id.* at 3.) His current "retropubic sling of choice" is the TVT Exact, which he continues to perform on a weekly basis. (*Id.*) If complications arise, Dr. Goldwasser has experience treating and managing those complications. (*Id.* at 4; Pls.' Ex. D (Goldwasser Dep.) 121:13-122:16.)

Dr. Goldwasser's report combines this extensive clinical experience with a reliance upon a large pool of scientific literature and studies as well as the evaluation of many physicians and medical organizations to form opinions to a reasonable degree of medical certainty. (Pls.' Ex. B (Goldwasser Report) at 1, 4.) The materials Dr. Goldwasser cites include Level 1 evidence and the official statements of medical societies. In addition to the materials directly cited in his report, Dr. Goldwasser also reviewed extensive amounts of medical literature identified on his reliance list. (*See generally* Pls.' Ex. E (General Reliance List).) Plaintiffs themselves acknowledge that Dr. Goldwasser's reliance list includes over 900 articles. (Pls.' Memorandum at 12; Pls.' Ex. D (Goldwasser Dep.) 43:22-44:10.) In short, Dr. Goldwasser's opinion merges his extensive training and experience as a surgeon, teacher, and inventor with an exhaustive wide-ranging review of the medical literature.

LEGAL STANDARD

Ethicon incorporates by reference the standard of review of *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *1-3 (S.D. W. Va. July 8, 2014).

ARGUMENT

I. Dr. Goldwasser is qualified to opine about the completeness of TVT's and TVT-Exact's warnings from a clinical perspective based on his education, training, clinical practice, and review of the medical literature.

Contrary to what Plaintiffs suggest, Dr. Goldwasser does not offer opinions on the "adequacy" of TVT's and TVT-Exact's labeling. Ethicon acknowledges this Court's prior rulings excluding urogynecologists and urologists from testifying about the "adequacy" of IFUs. See, e.g., Bethune v. Boston Sci. Corp., 2016 WL 2983697, at *5, 14-15 (S.D. W. Va. May 20, 2016); In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig., MDL No. 2327, 2016 WL 4536885, at *2 (S.D. W. Va. Aug. 30, 2016). Nevertheless, this Court has consistently held that they may testify about the specific risks associated with the product and whether those risks appeared in the IFU. See, e.g., Edwards, 2014 WL 3361923, at *13-14 ("Rather, as a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-O and whether those risks were adequately expressed on the TVT-O's IFU[,] . . . to render an opinion as to the completeness . . . of Ethicon's warning"). Dr. Goldwasser seeks to do just that – testify about the completeness of the warnings from the clinical perspective in light of the knowledge common to the relevant medical community. As this Court has previously recognized, "doctors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." Winebarger v. Boston Sci. Corp., No. 2:13-CV-28892, 2015 WL 1887222, at *15 (S.D. W. Va. Apr. 24, 2015) (quoting In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig., No. 3:09-md02100, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011)). Moreover, the governing legal standard underlying Plaintiffs' claims *require* the identification of those risks that are outside the scope of a device manufacturer's duty to warn because they are commonly known to surgeons who use the device at issue. It is this testimony that Dr. Goldwasser is uniquely qualified to provide.

In medical device product liability cases, there is no duty to warn of risks commonly known to implanting surgeons. *See Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers "not well known to the medical community."). In fact, the FDA device regulation explicitly noted by Dr. Goldwasser states that information can be omitted from labeling:

if, but only if, the article is a device for which directions, **hazards**, warnings and other information are commonly known to practitioners licensed by law to use the device.

21 C.F.R. §801.10(c) (emphasis added); *see also Wright ex rel. Trust Co. of Kansas v. Abbot Laboratories, Inc.*, 259 F.3d 1226, 1234 (10th Cir. 2001) (drug company had no duty to warn hospital of the danger of stocking different concentrations of saline solution in the same place); *Brown v. Drake-Willock Intern. Ltd.*, 530 N.W. 2d 510, 516 (Mich. App. 1995) (physician was sophisticated user of dialysis machine). Both the TVT and TVT-Exact IFUs restrict the class of surgeons who may use TVT and TVT-Exact. (*See* Ex. A, TVT IFU (English excerpts) at ETH.MESH.05225382; Ex. B, TVT-Exact IFU (English excerpts) at ETH.MESH.05799238.)
The TVT-Exact IFU, for example, advises that "Users should be familiar with surgical technique for SUI Sling placement and should be adequately trained in implanting the GYNECARE TVT EXACTTM Continence System before employing it." (Ex. B, TVT-Exact IFU at ETH.MESH.05799238.) Accordingly, plaintiffs' failure to warn claim depends on what

"hazards" were "commonly" known to surgeons familiar with pelvic floor repair as well as nonabsorbable meshes.

This Court has made clear that a physician may draw upon his clinical experience and review of relevant literature to give opinions on a product's safety and efficacy. *See, e.g., Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 585 (S.D. W. Va. 2014) (finding that a urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of mesh products). A physician is qualified to make a comparison between "the risks he perceives that the [device] poses to patients" and whether the labels "convey these risks to physicians." *Winebarger*, 2015 WL 1887222, at *15 (finding Dr. Shull qualified to give opinions on product labeling based on his clinical experience because his testimony did not touch on regulatory issues). Moreover, a physician is qualified to testify about the completeness of IFUs from a clinical perspective, despite lack of expertise with FDA regulations and requirements for warnings, or prior experience drafting IFUs. *Id.* at *6-7, 15 (finding Dr. Galloway qualified to provide opinion on IFUs based on clinical experience despite lack of familiarity with FDA rules or regulations for warnings).

Akin to Drs. Shull and Galloway in *Winebarger*, it is proper for Dr. Goldwasser to use his clinical experience and examination of a large pool of scientific literature to identify the risks that are commonly known to pelvic floor surgeons and give an opinion about whether risks allegedly omitted from the IFU were nonetheless commonly understood as existing risks from *a clinical perspective*:

As I have already noted above, all pelvic floor surgical procedures have certain commonly known risks. And the risks associated with the TVT and TVT-Exact procedures are almost all common to any pelvic floor surgery regardless whether mesh is utilized. These risks have been discussed in medical literature discussing pelvic floor surgeries for decades. It is commonly known that any surgery for stress urinary incontinence can potentially cause complications such as pelvic

pain, nerve/vessel injury, scarring, wound complications, bleeding, damage to surrounding organs, voiding problems/retention, dyspareunia, de novo or worsened incontinence, and the need for re-operation due to complications. Surgeons also commonly know that these complications can be mild, moderate, or severe, and temporary or long-term.

(Pls.' Ex. B (Goldwasser Report) 32-33; Pls.' Ex. D (Goldwasser Dep.) 69:15-19.) This opinion is particularly appropriate given that Dr. Goldwasser uses his knowledge and experience as an instructor to train young doctors in their residency. It is a far cry from Plaintiffs' argument that Dr. Goldwasser has opined on the adequacy of the TVT's and TVT-Exact's IFUs' compliance with regulatory requirements and medical device industry practices and lacks the qualifications to do so. (*See* Pls.' Memorandum at 5.)

Nevertheless, Plaintiffs may incorrectly argue for the first time on reply that the above opinion is precluded by this Court's rulings in *Tyree* and *Bellew*. In those cases, the Court excluded testimony from defense experts who offered opinions that the warnings were adequate merely because they included risks that the experts observed in their own practices. *See Tyree*, 54 F. Supp. 3d at 584 (S.D. W. Va. 2014); *Bellew v. Ethicon*, Inc., No. 2:13-cv-22473, Dkt. 265 at 33 (S.D. W. Va. Nov. 20, 2014). But, as is made clear above, Dr. Goldwasser's opinions rest not only on his own practice but on his historical review of the medical literature as well as his own experience in teaching medical professionals and the statement of the professionals themselves through their professional associations. This makes him well qualified to testify as to what risks are associated with mesh implants, and whether those risks are disclosed in the IFU or are otherwise "commonly known" to those surgeons. Notably, when Plaintiffs' experts have concluded that risks do occur based on such support, they are allowed to testify that the risk should have been included in the mesh warnings. It stands to reason that an expert employing this same methodology, while reaching a different conclusion, has also provided admissible

testimony. That Plaintiffs may disagree with Dr. Goldwasser's conclusion goes to weight, not admissibility and can be addressed on cross-examination. *Tyree*, 54 F. Supp. 3d at 532.

Simply put, it is disingenuous for Plaintiffs to suggest that Dr. Goldwasser's opinions are based solely on his personal experience. Even Plaintiffs' excerpts of Dr. Goldwasser's deposition transcript reference that he "relied not only on his personal, clinical experience, but also on the peer-reviewed literature[.]" (Pls.' Memorandum at 6.) He does not testify that his opinions are based *only* on his personal experience. In the cited testimony, Dr. Goldwasser confirms that his report is based on various literature, some of which were provided by Ethicon and others he obtained on his own. (Id.) In fact, Plaintiffs took issue with one article that Dr. Goldwasser relied on and questioned his failure to consider another article that purports to illustrate statistically significant incidence rates that Ethicon failed to include in its IFUs. (Id. at 7-8.) Yet, when Plaintiffs asked about this article, Dr. Goldwasser responded that the incidence rate was "inconsequential clinically." (Pls.' Ex. D (Goldwasser Dep.) 80:9-16.) In short, Plaintiffs have only provided an outline for cross-examination, not an argument for inadmissibility under Daubert. See, e.g., Trevino, 2016 WL 2939521, at *40 ("If there are certain device-specific publications that [Plaintiffs claim that Dr. Flynn] failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on crossexamination."); Huskey v. Ethicon, Inc., 29 F. Supp. 3d 691, 735 ("Dr. Johnson's failure to review particular documents goes to the weight of his opinion, not its admissibility."). Dr. Goldwasser's IFU opinions should be held admissible.

II. Dr. Goldwasser is well qualified to offer his opinions on the physical properties of polypropylene mesh and supports them with a reliable methodology.

Plaintiffs attempt to argue that Dr. Goldwasser should not be permitted to offer opinions on the physical properties of polypropylene mesh "because personal, clinical experience is not an

adequate foundation for such testimony." (Pls.' Memorandum at 9.) Contrary to Plaintiffs' arguments, however, Dr. Goldwasser is qualified to offer these opinions based on his clinical practice and review of medical literature. *See In re Neurontin Mktg., Sales Practices, & Prods. Liab. Litig.*, 612 F. Supp. 2d 116, 159 (D. Mass. 2009). While Dr. Goldwasser may not be a biomaterials expert, he can give *clinical* opinions on degradation, contracture, cytotoxicity, and mechanical and laser cut mesh based on his clinical experience implanting the mesh, studying its properties, teaching its use by surgeons, and review of the medical literature and medical society materials. Indeed, Dr. Goldwasser's report and disclosures reference and rely on extensive relevant literature on these very subjects. (*See generally* Pls.' Ex. B (Goldwasser Report); Pls.' Ex. E (General Reliance List); Pls.' Ex. F (Supplemental Reliance List).)

A. Dr. Goldwasser's testimony regarding degradation, mesh contraction and appropriate pore weight and size is reliable and admissible.

Dr. Goldwasser opined that "my clinical experience and analysis of the body of data, including the studies cited in my report, supports my opinion that Ethicon's polypropylene mesh does not degrade in vivo, or if does, that such degradation does not have any clinically significant effect." (Pls.' Ex. B (Goldwasser Report) at 29-30.) He also opined that "[i]n my practice, I have not seen a single case of contraction, and I am not aware of any literature that describes contraction associated with TVT or TVT Exact" and that pore size "can impact infectious risk and tissue integration." (*Id.* at 9, 27.) Plaintiffs argue that Dr. Goldwasser is not qualified to offer these opinions and that he offers no reliable methodology for them. These arguments should be rejected.

Dr. Goldwasser is qualified to offer his opinions. In *Mathison v. Boston Scientific Corporation*, this Court found that a board-certified urologist, Dr. Lonny S. Green, who had conducted nearly 3,000 sling procedures and practiced for twenty years was qualified to opine

that the mesh product does not shrink, contract, degrade, or cause systemic infections. No. 2:13-CV-05851, 2015 WL 2124991, at *28 (S.D. W. Va. May 6, 2015). Like Dr. Green, Dr. Goldwasser has sufficient familiarity and experience with transvaginal mesh generally and the TVT and TVT-Exact in particular to provide reliable opinions on whether they shrink, contract, or degrade. Dr. Goldwasser has implanted over a thousand TVT procedures (mainly TVT and TVT-Exact), and when mesh complications arise, he treats and manages those complications. (Pls.' Ex. B (Goldwasser Report) at 4 (stating that Dr. Goldwasser's practice also involves "treating and managing complications associated with both **mesh** and non-mesh surgical procedures." (emphasis added).); Pls.' Ex. D (Goldwasser Dep.) 121:13-122:16.) He also has "considerable experience treating complex female pelvic pain, sexual dysfunction, complex urinary incontinence, recurrent urinary tract infections, and other pelvic complaints in patients." (Pls.' Ex. B (Goldwasser Report) at 4-5.) Dr. Goldwasser is therefore qualified to opine that TVT and TVT Exact do not degrade, contract, or cause infections.

Further, Dr. Goldwasser has demonstrated the reliability of his methodology. This Court, in *Mathison*, also found that the doctor's clinical experience and review of scientific literature were sufficiently reliable bases in forming his opinions about the mesh product's physical properties. *See Mathison*, 2015 WL 2124991, at *28. Similarly, here, in addition to his extensive clinical experience, Dr. Goldwasser reviewed over 900 articles in his General Reliance List, which directly contradicts Plaintiffs' argument that he "pick[s] and choose[s]" his articles. Dr. Goldwasser's deposition testimony confirms that he is knowledgeable regarding the substance of the literature. (*See, e.g.*, Pls.' Ex. D (Goldwasser Dep.) 74:1-82:18.) Thus, Dr. Goldwasser's clinical experience and, in particular, his review of the scientific literature

adequately qualifies him to opine on the physical properties of TVT and TVT-Exact, including degradation, contraction, and pore weight and size.

This is consistent with prior rulings in this MDL, where this Court has allowed urologists, gynecologists, and urogynecologists with extensive experience in treating stress urinary incontinece, including the mesh devices at issue, to testify that they have not experienced certain alleged physical properties (such as degradation) in the mesh devices at issue. See, e.g., Trevino v. Boston Scientific Corp., 2016 WL 2939521, at *45 (S.D. W. Va. May 19, 2016) (finding that a practicing urogynecologist who is board-certified in obstetrics and gynecology and had extensive experience in treating stress urinary incontinence and pelvic organ placing, including Prefyx and Uphold mesh slings, was "qualified him to testify that he has not experienced certain alleged physical properties in the defendant's Uphold and Prefyx devices."); see also id. at *5 (finding that urologist Niall Galloway's "clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage and contraction"); id. at *33 (allowing testimony of defense expert Patrick Culligan, M.D.); Huskey, 29 F. Supp. 3d at 706-07, 735 (rejecting similar challenges to plaintiff expert Bruce Rosenzweig, M.D., and defense expert urogynecologist Harry Johnson, M.D.); Tyree, 54 F. Supp. 3d at 550, 585 (rejecting similar challenge of plaintiff expert Donald Ostergard, M.D. and defense expert Lonny Green, M.D.); Jones v. Bard, Inc., No. 2:11-cv-00114, [Doc. 391], at 6-9. Accordingly, Plaintiffs' request to exclude Dr. Goldwasser's opinion on degradation and mesh contraction should be dismissed.

B. Dr. Goldwasser should be permitted to testify on cytotoxicity and cancer risk.

Dr. Goldwasser opined that "I am not aware of any evidence that polypropylene, when used as designed for its intended purpose as a mesh implant or as a suture material, has any

clinically significant cytotoxic or cancer-causing effect." (Pls.' Ex. B (Goldwasser Report) at 30.) Plaintiffs contend that Dr. Goldwasser cannot offer such opinions because he is not an expert in gynecology oncology and he received no training in it. (Pls.' Memorandum at 12-13.) Although Dr. Goldwasser may not be a gynecological oncologist, he was formally trained in it. (Pls.' Ex. D (Goldwasser Dep.) 14:24-15:2 ("Q. Gynecological oncology, did you receive specific formal training in that as part of your residency and/or fellowship? A. In residency.").) Because of his clinical experience, which incorporates his gynecologic oncology training, Dr. Goldwasser is adequately qualified. Further, his report identifies relevant literature on this topic. (See, e.g., Pls.' Ex. B (Goldwasser Report) at 31 (citing article that concludes polypropylene is not associated with carcinogenesis.) Dr. Goldwasser's review of relevant literature and reliance on them, combined with his experience as a surgeon, teacher, inventor, provide a reliable basis for his opinions on cytotoxicity and cancer risks.

C. Dr. Goldwasser is qualified to offer his opinions on the lack of clinical distinction between mechanical cut and laser cut mesh.

Dr. Goldwasser's extensive clinical experience using mesh and review of the relevant literature qualifies him to call into question Plaintiffs' scientific basis for their assertion that Ethicon created laser-cut mesh in response to alleged clinical problems from mechanical cut mesh. Dr. Goldwasser opined that in his practice, he has not noted any clinical difference between the two types of mesh and continues to have no preference between the two. (Pls.' Ex. B (Goldwasser Report) at 28.) He also indicated that he reviewed clinical studies on TVT, "which consistently demonstrate its efficacy, durability and safety [and] have not been shown to have a difference in results pre and post 2007 when laser cut mesh became available." (*Id.*) Moreover, when questioned on the subject at his deposition, Dr. Goldwasser testified that he reviewed Ethicon's company documents which found no "clinical relevance" between

mechanical cut and laser cut mesh. (Pls.' Ex. D (Goldwasser Dep.) 136:18-137:17.) Thus, Plaintiffs' Motion on this point should be rejected for substantially the same reasons outlined in Point II (A).

III. Dr. Goldwasser's unfamiliarity with Boston Scientific's ProteGen sling is irrelevant to his qualifications to testify regarding the TVT and TVT-Exact.

As if an afterthought, Plaintiffs attempt to summarily suggest that because Dr. Goldwasser was unfamiliar with Boston Scientific's ProteGen sling, which was a "predicate device" for TVT's 510(k) clearance in 1997, he is not qualified to opine and testify on TVT and TVT-Exact. (Pls.' Memorandum at 15.) Any such argument should be denied because it is wholly irrelevant to *Daubert* scrutiny. The ProteGen sling is a completely distinct product created by a different manufacturer. Although the ProteGen sling was listed as a predicate device for TVT, only three aspects of the 510(k) submissions were similar: (1) the intended use as a pubourethral sling to treat stress urinary incontinence, (2) the clinical mechanism of "urethral support," and (3) a similar incision location in the anterior vaginal wall. All other aspects of the devices were and are different. Indeed, the conditions that ultimately led to ProteGen's recall in 1999 stemmed from its differences from TVT, not its similarities. Nevertheless, nothing about the recall of the ProteGen sling speaks to Dr. Goldwasser's qualifications to opine and testify about TVT and TVT-Exact. Plaintiffs' Motion on this point should therefore be denied.

IV. Dr. Goldwasser's alleged "bias" against "attorney advertising" is, at most, an issue for cross-examination.

In their moving papers, Plaintiffs expend substantial ink arguing that Dr. Goldwasser's opinions are unreliable and should be discounted because he is "biased" against "attorney advertising" in the transvaginal mesh litigation. (Pls.' Memorandum at 15-18.) But, such an attack only goes to the weight of Dr. Goldwasser's testimony, not its admissibility. Plaintiffs can

test any alleged bias Dr. Goldwasser has through cross examination. *See Holcomb v. Boston Scientific Corp.*, 2016 WL 3189787, at *17 (S.D. W. Va. June 7, 2016) ("Bias and witness credibility are appropriate topics for cross-examination."). Thus, Plaintiff's Motion as to this argument is unavailing under *Daubert* and should be denied.

CONCLUSION

For the foregoing reasons, the Court should DENY Plaintiffs' motion to exclude or otherwise limit the opinions and testimony of defense expert Steven Goldwasser, M.D., in its entirety.

Respectfully submitted,

August 29, 2017

/s/ Christy D. Jones

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CERTIFICATE OF SERVICE

I hereby certify that on August 29, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

/s/ Kelly S. Crawford
Kelly S. Crawford

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